December 2016

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

2017 Board Meeting Schedule Is Set

Idaho State Board of Pharmacy meetings play an important role in the regulation of pharmacy practice in Idaho. The Board extends an open invitation to all pharmacists, technicians, and other interested parties to attend and actively participate in these meetings. Your feedback and engagement can help ensure that public health and patient safety are optimized in our state.

- January 12-13 – Boise, ID
- March 9 (Strategic Planning) – Boise
- April 13-14 – Boise
- June 8 – Boise
- July 12 – Conference Call
- August 1-2 (Negotiated Rulemaking) – Boise
- October 25-26 (Proposed Rulemaking) – Boise

Please visit the Board's website for more information in advance of each meeting, including meeting agendas, minutes, and public meeting materials. Public meeting materials are typically available for download 48 hours prior to each meeting.

Licensees or members of the public seeking to request an agenda item may contact the Board's executive director, Alex Adams, for consideration (alex.adams@bop.idaho.gov; 208/334-2356).

The deadline to request an agenda is posted for each meeting on the Board's website and is typically six weeks prior to the meeting date.

Announcing Free Pharmacist-in-Charge Training Program

The Board has launched a free home study law continuing pharmacy education (CPE) program to assist current or future pharmacists-in-charge (PICs) in better understanding their roles and responsibilities of this position in Idaho. The program is accredited for two hours of Board-approved law CPE.

The program specifically reviews the following elements:

- Who may serve as a PIC;
- What a PIC should do as he or she begins his or her new role;
- What ongoing activities a PIC is responsible for with respect to reporting requirements, record keeping, and license maintenance for the pharmacy team;
- What to expect on a pharmacy inspection;
- How to handle an impaired employee; and
- What a PIC should do upon completion of the role.

The program may be accessed on the Board's website at *https://bop.idaho.gov*.

Pharmacy-Based Drug Take-Back Programs

In 2014, Drug Enforcement Administration (DEA) passed the final ruling authorizing ultimate users to transfer controlled substances (CS) to an authorized collector for safe, secure, and responsible disposal. Retail pharmacies, hospitals, and clinics with on-site pharmacies, among others, may modify their DEA registration to become authorized collectors of CS. There is no fee to modify the registration, and the modification can be accomplished through DEA's website at *https://apps.deadiversion.usdoj.gov/webforms2/spring/login?execution=e1s1*.

Idaho law allows pharmacies to serve as collectors for disposal if the program is conducted in compliance with federal law. In addition to modifying the DEA registration, pharmacies must follow specific requirements related to collection receptacle placement, use of inner liners, and reverse distribution, among others. To assist pharmacists with these rules, the Board will issue a free home study CPE program, accredited for one-half hour of Board-approved law CPE. The program may be accessed in January 2017 on the Board's website at *https://bop.idaho.gov*.

Can I Fill a Prescription Written by a Pharmacist?

Pharmacist prescriptive authority for certain products has led to new opportunities for pharmacists to improve patient care outcomes. While this trend may seem new to the public, pharmacists in all 50 states have had prescriptive authority for at least some products dating back nearly four decades. Still, pharmacists routinely call the Board to determine the legitimacy of a pharmacist-prescribed medication.

As a review, Idaho-licensed pharmacists may **independently** prescribe the following products:

- Dietary fluoride supplements;
- Immunizations to patients six years of age or older;
- Opioid antagonists to a patient or to a person in a position to assist a patient; and
- Epinephrine auto-injectors to a patient or to a person in a position to assist a patient, or to a facility in which allergens may be encountered.

While it is common for a pharmacist who prescribes these products to also dispense them, this does not have to be the case. A pharmacist in one setting could write a prescription for these products that are then dispensed in a separate setting.

Similarly, pharmacists in other states have autonomous prescriptive authority for certain products, such as Oregon pharmacists prescribing contraceptives. Such a prescription can be filled in Idaho as long as it was generated lawfully in the state from which it was issued.

continued on page 4

FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

IDAHO STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

Pharmacist prescriptive authority can be augmented by a collaborative practice agreement (CPA). CPAs represent an agreement between a pharmacy or pharmacist and a prescriber, authorizing the pharmacist to perform certain services on behalf of the prescriber, such as initiating or modifying medication regimens. A recent report to the United States surgeon general highlighted the important role that CPAs play, and a growing body of evidence demonstrates the positive patient care outcomes that CPA models of care can achieve.

The Board's CPA rule (Rule 310) specifies the minimum requirements of a CPA. Recently, several ambulatory care pharmacists have entered into a CPA and are adjusting medication doses or adding on new medications to close a gap in care. Such prescriptions generated under a CPA may be filled the same as any other prescription. All minimum requirements of a valid prescription drug order (Rule 111) must be present on the prescription.

PMP Enrollment and Delegate Registration

Currently, 90% of Idaho pharmacists are registered to access the state's prescription monitoring program (PMP). Registration is easy, free, and one-time and can be accomplished by visiting *https://idaho.pmpaware.net.*

As of July 1, 2016, pharmacists may also designate up to four delegates to check the PMP on their behalf. This is a critical tool in streamlining access to needed PMP information while removing the administrative burden placed on pharmacists. While the number of delegates is growing, the majority of Idaho pharmacists have still not taken advantage of this benefit. The Board strongly encourages you to consider designating a delegate. To do so, the following must occur:

(1) A proposed delegate must submit a registration for access to the Board by visiting *https://idaho.pmpaware.net/identities/new* and verifying his or her email address using the link sent to him or her by the system. **(Check your junk or spam folders.)**

(2) As part of the registration process, a proposed delegate must enter his or her supervising pharmacist's email address.

(3) The supervising pharmacist must log in to his or her PMP account and authorize the proposed delegate. Delegates associated with a pharmacist's account are displayed in a table found at User Profile → Delegate Management. From this location, a supervising pharmacist is able to approve or reject new delegates or deactivate existing delegates from his or her account. To approve, the user selects the delegate and clicks the approve button. To reject or deactivate, the user selects the delegate and clicks the reject button. This removes the delegate from the supervisor's list.

(4) Board staff confirms that all requirements have been met for the delegate's user account and approves the account. The delegate will receive an email stating that his or her account has been approved and is now active.

For more information, please contact Teresa Anderson or Ellen Mitchell at the Board office at 208/334-2356 or email at teresa.anderson@bop.idaho.gov or ellen.mitchell@bop.idaho.gov if you have any questions or if you are unable to access the system.

Reporting Zero Days Supply to the PMP

The Board's PMP has been receiving CS prescription data where the days supply has been reported as zero. The "days supply" is a required field in the prescription data records being submitted and should reflect the estimated number of days the medication will cover. A zero days supply is not considered a valid amount. Any pharmacy that has been submitting zero days supply must correct those records and resubmit them as a "revised" record. As of October 24, 2016, any CS prescription records reported to the PMP with a zero days supply will be rejected. Please contact Teresa Anderson at the Board office at 208/334-2356 or email at teresa .anderson@bop.idaho.gov if you have any questions. The Board may consider possible action in cases in which incorrect data is reported to the PMP.

Help Is Available for Impaired Pharmacists Through Idaho PRN

The Board subsidizes the state's Pharmacist Recovery Network (PRN). The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence, including intervention, consultation, monitoring, advocacy, education, and support. If you need confidential help or know an associate who does, please contact the program's vendor, Southworth Associates, by phone at 866/460-9014.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read it carefully.

The *Idaho State Board of Pharmacy News* is published by the Idaho State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Alex J. Adams, PharmD, MPH - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager